



January 15, 2019

Docket # USTR-2018-0036

Edward Gresser
Chair of the Trade Policy Staff Committee
Office of the United States Trade Representative

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to respond to the U.S. Trade Representative's (USTR) request for comments on negotiating objectives for a United States (US) – United Kingdom (UK) Trade Agreement.

BIO is a non-profit organization with a membership of more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in almost all 50 States and a number of foreign countries. BIO's members research and develop health care, agricultural, industrial, and environmental biotechnology products. The vast majority of BIO members are small to medium sized pre-commercial companies.

Advances in biotechnology innovation have had a transformative impact on many sectors of the economy — from advances in healthcare to improved plants that are key to feeding the world to industrial biotechnology applications that are leading to bio-based fuels, chemicals and products that can protect our environment and herald a new age of sustainable development.

Bioscience industries employed 1.7 million people in 2014 across more than 77,000 U.S. business establishments.¹ The broader employment impact of the U.S. biosciences is the creation an additional 7.5 million jobs throughout the economy. Taken together, these direct, indirect, and induced bioscience jobs account for a total employment impact of 9.3 million jobs.²

The industry continues to pay high wages, reflecting the high skills and education requirements of an innovative workforce, with the average U.S. bioscience worker earning nearly \$95,000 per year, or 85% greater than the private sector average. Since 2001, bioscience wages have grown substantially faster than overall private sector wages.³ The bioscience industry is also well distributed geographically in the United States: 32 states and Puerto Rico have an employment specialization in at least one bioscience subsector, and 222 of 381 U.S. metropolitan areas, have employment in at least one biotechnology sector.⁴

BIO supports the U.S. government entering negotiations with the United Kingdom as an opportunity to grow U.S. exports and create U.S. jobs. We would strongly urge the U.S. government to build on the recent U.S.-Mexico-Canada agreement and that the agreement

¹ "The Value of Bioscience Innovation in Growing Jobs and Improving Quality of Life 2016", https://www.bio.org/sites/default/files/BIO%202016_Report_FINAL_DIGITAL.pdf at 2.

² *Id.*

³ *Id.*

⁴ *Id.*

comprehensively addresses the biotechnology sector as an engine for growth for both economies.

BIO Priorities for a US-UK Trade Agreement

BIO considers the potential of a US-UK Agreement to be a significant opportunity to achieve a world-class 21st century agreement for the biotechnology industry. Both the US and UK are home to innovative biotech and biopharma companies and world-renowned academic institutions, a trade agreement between the two economies should be focused on fostering an environment for biotechnology industry to thrive. BIO recognizes the challenges presented by the uncertainties surrounding the Brexit negotiations and the nature and timing of UK's exit from the European Union will impact trade agreement priorities. As the UK's post-Brexit relationship with the EU becomes clearer, the biotech sector will be able to provide more detailed information of the sector's priorities. Nevertheless, BIO's recommended negotiating objectives for the US-UK agreement build on recent agreements, including the US, Mexico, Canada (USMCA) Agreement, the US-Korea (KORUS) Free Trade Agreement and negotiating objectives recently proposed in the US-EU and US-Japan agreements.

Agricultural Innovation

Advances in agricultural innovation and the ability to adopt new production technologies remains a critical priority for the U.S. agricultural sector, and a trade agreement with the UK could present an opportunity to support the integration of current and future innovations into global supply chains.

The agriculture sector is experiencing major breakthroughs in technologies that hold great promise for solving or mitigating significant human and animal health and welfare, food security, and environmental challenges. Unjustified sanitary and phytosanitary measures present a significant barrier to not only the trade for US agricultural goods to many markets around the world, but also the commercialization of these technologies. This challenge is perhaps most acute in the EU, where unscientific trade barriers substantially contribute to the trade deficit and limit economic growth in the US. In this case a Brexit agreement that enables UK independence from the EU with regards to the regulation of agricultural technologies creates an opportunity for two like-minded countries to find new approaches to support innovation and trade.

BIO welcomes the potential for a US-UK trade agreement to ensure regulation of agricultural innovation is science-based, transparent and predictable. BIO seeks to continue to build upon the improvements to the global policy environment for agricultural biotechnology achieved in the USMCA, as well as seek gains in the policy environment for veterinary medicines. Predictable, science and risk-based regulation is critical to enabling innovation and attracting investment, especially for small and medium enterprises (SME). BIO encourages the US and UK to utilize this opportunity to improve the global policy environment and better enable SMEs to operate in this space. BIO welcomes the opportunity to work with the Administration in achieving these objectives.

BioPharmaceuticals

There is much that aligns the US and UK biopharmaceutical industry. Many US companies maintain European Headquarters in the UK and many UK companies seek to expand first into

the United States. The US-UK agreement should look to encourage and ease this exchange and collaboration. Facilitating ongoing international science collaboration would benefit both US and UK companies.

Regulatory

With regards to the impact of Brexit on biopharmaceuticals it is critical to avoid a no-deal scenario. Complicated supply-chains, regulatory process and international cooperation will be negatively impacted if the UK has a disorderly exit from the EU.

In the event of a Brexit deal, the UK Government has stated its intention for the UK regulator, MHRA, to seek a medicines regulatory cooperation/alignment agreement with the EU regulator, European Medicines Agency (EMA). The EU agreed to this intent in the joint UK/EU Political Declaration which focused on a possible future relationship. However, these negotiations have not commenced (and may not if there is a no deal Brexit), and therefore there is little clarity on whether medicines regulatory cooperation is achievable and to what extent it would be.

Regardless of the outcome, BIO strongly supports close regulatory cooperation with the UK and to model US-UK cooperation on what has been achieved with Europe, including quickly reestablishing a Mutual Recognition Agreement on Good Manufacturing Practices. The "grandfathering" of the US-EU MRA to US-UK MRA would provide certainty and business benefit to our member companies. This should be in place whatever Brexit scenario occurs and once in place there should be consideration given to how it could be expanded.

Pricing and Reimbursement

BIO welcomes progress made in recent U.S. bilateral trade agreements, in particular with USMCA and Korea, to require transparency and accountability of foreign government pricing and reimbursement of biopharmaceuticals, to ensure market access and reward for innovation. BIO believes that to ensure that US trading partners are allowing fair, non-discriminatory access to new medicines, and shouldering a fair share of the costs of innovation, that any modern trade agreement, including a US-UK agreement should build on these provisions. Such provisions should include clear timetables for pricing and reimbursement decisions, clear justifications given for government decisions, the right to appeal decisions to an independent body, and provisions that ensure fair reward for innovative products within the NHS system. A thriving biotech industry will in particular require that sound valuation and financing decisions are made with respect to new technologies such as gene and cell therapies and gene-editing techniques for treating diseases.

Intellectual Property

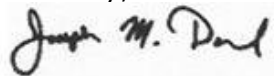
The US and UK should seek to establish a world-class agreement on IP and should address cooperation in third countries as part of this effort. As such, in accordance with the Trade Promotion Authority Act requiring the US government to leverage trade agreements to bring our trading partners in line with US standards for intellectual property rights, BIO strongly believes the U.S. standards of data protection for biologic products (12 years) remains the gold standard and should be the basis for negotiations with the United Kingdom. The recently concluded USMCA presents a strong foundation from which to build and achieves a standard closer than U.S. law. Further, with respect to Brexit and a no-deal outcome, any RDP provided in the UK should be based on the date of first marketing approval in the UK, not the EU or

elsewhere. In addition, BIO would welcome strong provisions around patent enforcement and patent term restoration.

Conclusion

Thank you for the opportunity to comment, BIO looks forward to working with the US government as discussions around a US-UK commence.

Sincerely,

A handwritten signature in black ink, reading "Joseph M. Damond". The signature is written in a cursive, flowing style.

Joseph M. Damond
Executive Vice President, International Affairs